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PHILIPS

Philips Medical Systems

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510(K) SUMMARY

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

Company Name	:	Philips Medical Systems North America Company.
Address	:	710 Bridgeport Avenue Shelton, CT 06484.
Registration No.	:	1217116
Contact person	:	Peter Altman
Device (Trade) Name	:	**Synergy Head/Neck coil**
Classification Name	:	Magnetic Resonance Specialty Coil.
Classification	:	Class II.
Product code	:	MOS
Performance standards	:	NEMA voluntary standards, FDA MRDD guidance's, UL and IEC 601 appropriate safety standards and/or draft standards are used.
Common/Usual Name	:	RF external **Synergy Head/Neck coil**

Predicate Device(s):

The Synergy Head/Neck Coil is comparable with the other Philips RF synergy coils which have been commercially cleared as part of the MRDD Philips GYROSCAN INTERA Release 7 series systems with FDA (ref. K992533).

Intended use:

The **Synergy Head/Neck coil** combination is meant for MR imaging of the head and neck region , e.g., brain , cervical spine, and carotid MRA imaging. It is compatible to be used with the Philips GYROSCAN systems which are indicated for use as diagnostic devices that produce transverse, sagittal, coronal and oblique cross-sectional images, spectroscopic images and/or spectra, based upon ^{1}H and ^{31}P metabolites, and that display the internal structure and/or function of the head, body or extremities. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

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Device Description and Technological Characteristics:

The **Synergy Head/Neck coil** is a synergy RF receive only coil which is compatible for use with the MRDD Philips GYROSCAN systems.
The Synergy Head/Neck coil is a Quadrature Head Coil (QHC) combined with a synergy neck coil (SNC) to extend the coverage for imaging to the neck region. The QHC is an existing coil that has been incorporated as part of the commercially available Philips GYROSCAN INTERA Release 7 series (ref. K992533). The Synergy Head/Neck coil is an external RF coil made of routinely used materials. The technological characteristics are based on the same concept as with the other Philips RF synergy coils that have been cleared as part of the MRDD Philips GYROSCAN INTERA Release 7 series systems (ref. K992533).

The **Synergy Head/Neck coil** is available in two versions, i.e., for the 1.5 Tesla and 1.0 Tesla MRDD Philips GYROSCAN systems.

General Safety and effectiveness:

The safety and effectiveness of the **Synergy Head/Neck coil** are the same as with the other Philips RF synergy coils which have been cleared as part of the MRDD Philips GYROSCAN INTERA Release 7 series systems (ref. K992533).
It does not induce other safety issues and warnings than already valid for the current cleared RF external coils.

Substantial Equivalence:

The Synergy Head/Neck coil is substantially equivalent to the other Philips RF synergy coils which have been cleared for commercial distribution as part of the MRDD Philips GYROSCAN INTERA Release 7 series systems (ref. K992533).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2000

Peter Altman
Director of Regulatory Affairs
Philips Medical Systems
North America Company
710 Bridgeport Avenue
P.O. Box 860
Shelton, CT 06484-0917

Re: K001331
Synergy Head/Neck Coil
Dated: April 25, 2000
Received: April 27, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 MOS

Dear Mr. Altman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K001331
Device Name : **Philips Synergy Head/Neck Coil.**

Indication For Use :

The **Synergy Head/Neck coil** combination is meant for MR imaging of the head and neck region , e.g., brain , cervical spine, and carotid MRA imaging. It is compatible to be used with the Philips GYROSCAN systems which are indicated for use as diagnostic devices that produce transverse, sagittal, coronal and oblique cross-sectional images, spectroscopic images and/or spectra, based upon ^{1}H and ^{31}P metabolites, and that display the internal structure and/or function of the head, body or extremities. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Lejeune
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001331